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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,303	07/06/2001	Gcort Maertens	2752-52	3515

23117 7590 02/25/2003

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,303

Applicant(s)

MAERTENS ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 67-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1648

DETAILED ACTION

Amendment filed on 01/07/2003 has been acknowledged. Claims 89-90 have been amended. Claims 67-96 are pending.

Election/Restrictions

1. **The Office apologizes for the typographical errors that appeared in the previous Office Action mailed on November 25, 2002. The previous Office Actions on Restriction/Election requirement mailed on July 25, 2002 and Nov. 05, 2002 are hereby vacated. The Office regrets any inconvenience these actions may have caused Applicant. A new Office Action on Restriction/Election is issued on the requirement of U.S.C. 121:**

- I. Claims 67-77, 79 and 85-91 and 95-96 drawn to a recombinant vector and a composition comprising the vector comprising a HCV envelope protein classified in class 430, subclass 320.1.

Upon election of Group I, Applicant is additionally required to elect a single sequence selected from the group consisting of SEQ ID NO 3, 5, 7, 9, 11, 13, 21, 23, 25, 27, 29, 31, 35, 37, 39, 41, 43, 45, 47 and 49, to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, it derived from different genome of HCV isolates and each of them has different patentable weight. The search for polypeptide of SEQ ID NO: 3 does not need to search the polypeptide of SEQ ID NO: 7.

Upon election of Group I, Applicants are required to further elect one of vectors from the group consisting of (i) vaccinia virus vector (claim 88), (ii) avipox vector (89), (iii) and Ankara Modified virus vector (90) and (iv) baculovirus vector (91) for the examination on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the vector has different structure and patentable weight. Furthermore, the search of vaccinia virus vector does not necessarily need to search Ankara Modified virus vector.

- II. Claims 78, drawn to a method for immunization of human with a vector comprising a HCV envelope protein, classified in class 424, subclass 93.1 .

Art Unit: 1648

III. Claims 80, drawn to a host cell and a recombinant protein produced by the host cell, classified in class 435, subclass 325.

IV. Claims 81-83 and 92-94, drawn to a recombinant fusion protein of HCV envelope protein, classified in class 424, subclass 228.1.

Upon elect any one of groups IV, Applicants are required to further elect one of host cells from the group consisting of (a) mammalian cells (claim 92), (b) bacterial cells (93), (c) and fungal cells for the examination on the merits. This is not a species election because each kind of host cells has different structure and function, which is also with different patentable weight.

V. Claim 84, drawn to a method for purifying a HCV envelope protein, classified in class 435, subclass 69.1.

Upon elect any one of groups I-IV, Applicants are required to further elect one of the envelope fusion protein from the group consisting of (1) E1, (2) E2 and (3) and E1/E2 for the examination on the merits. This is not a species election because each of the fusion protein has different structure and function, which also has different patentable weight.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different products e.g. the product of group I is a vector, whereas the product of Group III is a host cell.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed in group I can be made by another and materially different process, such as protein synthesis, rather than recombinant DNA technique.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

Art Unit: 1648

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed in Group II can be practiced with another materially different product, such as an antibody against HCV envelope protein antigen rather than a vector expressing an antigen polypeptide in group I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for one of the Groups are not required for another one of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

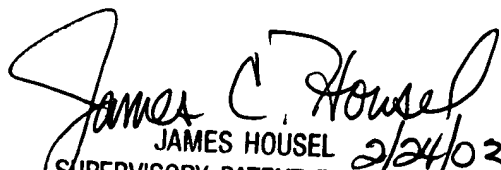
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

February 21, 2003.


JAMES HOUSEL 2/24/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600